Reference number(s)
2233-C

Specialty Guideline Management bortezomib products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Velcade	bortezomib
Boruzu	bortezomib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1-3]

- Treatment of adult patients with multiple myeloma
- Treatment of adult patients with mantle cell lymphoma

Compendial Uses[4-9]

- Systemic light chain amyloidosis
- Waldenström macroglobulinemia/lymphoplasmacytic lymphoma
- Multicentric Castleman disease
- Adult T-cell leukemia/lymphoma
- Antibody mediated rejection of solid organ
- Acute lymphoblastic leukemia
- Follicular lymphoma
- Kaposi sarcoma

- Pediatric classic Hodgkin lymphoma
- POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome
- Plasma cell-related Monoclonal Immunoglobulin Deposition Disease (MIDD)
- Plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS)

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Multiple Myeloma[1-4]

Authorization of 12 months may be granted for the treatment of multiple myeloma.

Mantle Cell Lymphoma[1-4]

Authorization of 12 months may be granted for the treatment of mantle cell lymphoma.

Multicentric Castleman Disease[4]

Authorization of 12 months may be granted for the treatment of multicentric Castleman disease as subsequent therapy.

Systemic Light Chain Amyloidosis[4,8,9]

Authorization of 12 months may be granted for the treatment of systemic light chain amyloidosis.

Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma[4,8,9]

Authorization of 12 months may be granted for the treatment of Waldenström macroglobulinemia/lymphoplasmacytic lymphoma.

Adult T-Cell Leukemia/Lymphoma[4]

Authorization of 12 months may be granted for the treatment of adult T-cell leukemia/lymphoma when the requested medication will be used as a single agent for subsequent therapy.

Antibody Mediated Rejection of Solid Organ[5-8]

Authorization of 12 months may be granted for the treatment of antibody mediated rejection of solid organ.

Acute Lymphoblastic Leukemia[4]

Authorization of 12 months may be granted for the treatment of acute lymphoblastic leukemia.

Follicular Lymphoma[8]

Authorization of 12 months may be granted for the treatment of relapsed or refractory follicular lymphoma.

Kaposi Sarcoma[4]

Authorization of 12 months may be granted for the treatment of Kaposi sarcoma as subsequent therapy.

Pediatric Classic Hodgkin Lymphoma[4]

Authorization of 12 months may be granted for the treatment of relapsed or refractory pediatric classic Hodgkin lymphoma.

POEMS (Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal Protein, Skin Changes) Syndrome, plasma cell-related Monoclonal Immunoglobulin Deposition Disease (MIDD), plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS)[4, 10]

Authorization of 12 months may be granted for treatment of POEMS syndrome, plasma cell-related MIDD, or plasma cell-related MGRS.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

For all indications, dosing does not exceed 1.6 mg/m^2 per dose and does not require more than 7 doses per 30-day period.[4]

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Velcade [package insert]. Cambridge, MA: Takeda Pharmaceuticals America, Inc.; August 2025.
2. Boruzu [package insert]. Telangana, India; Amneal Oncology Pvt. Lt.; July 2025.
3. bortezomib [package insert]. Somerset, NJ: Somerset Therapeutics, LLC.; May 2025.
4. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed September 10, 2025.
5. Ejaz NS, Alloway RR, Halleck F, et al. Review of bortezomib treatment of antibody-mediated rejection in renal transplantation. Antioxid Redox Signal. 2014;21(17):2401-2418.
6. Blanco B, Sanchez-Abarca LI, Caballero-Velazquez T, et al. Depletion of alloreactive T-cells in vitro using the proteasome inhibitor bortezomib preserves the immune response against pathogens. Leuk Res. 2011;35(10):1412-1415.
7. Claes DJ, Yin H, Goebel J. Protective immunity and use of bortezomib for antibody-mediated rejection in a pediatric kidney transplant recipient. Pediatr Transplant. 2014;18(4):E100-E105.
8. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed September 10, 2025.
9. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: http://www.micromedexsolutions.com. Accessed September 10, 2025.
10. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma. Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed October 7, 2025.